

Consent Form for Non-Interventional Research Study Participation

Study Title: An Observational Study Assessing the Clinical Effectiveness of the VeriStrat® Test and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer

Study #: BDX-00146

Sponsor: Biodesix, Inc.

Study Doctor: Dependent on Study Site

Telephone Number: Dependent on Study Site

After Office Hours: Dependent on Study Site

For California participants: Before you read this consent form, you should read and sign a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you haven't already received one.

1.0 Introduction

You are being asked to participate in a non-interventional research study. Your participation is voluntary. If you choose to participate, you may elect to withdraw your consent at any time.

You are being asked to be in this research study because you have Non-Small Cell Lung Cancer (NSCLC) and your doctor already has or will use a commercially available blood test, called VeriStrat®, to help determine how to treat the NSCLC and/or to help determine the prognosis.

If you choose to participate in this study, you will be asked to sign this consent form, confirming the study has been explained to you, all your questions have been answered, and that you give your permission to participate. Being in this study will not change your regular medical care from your doctor.

2.0 Purpose

The purpose of this study is to collect information about how your doctor uses the results of the VeriStrat blood test to choose treatment for your NSCLC. Understanding how VeriStrat results influence doctors' decisions and patients' outcomes may help doctors to better treat NSCLC in the future.

This study will also look to establish whether new investigational tests can help better predict certain medications for certain patients. These tests are only for research purposes at this time.

3.0 Study Activities

This is a large multi-site national study that includes 2,000 people that are 18 years of age or older with NSCLC; each participant will be followed for up to 18 months.

After you sign this form, your personal NSCLC-related medical history will be recorded in the study database. Your demographics, including your gender, age at time of consent, race, and ethnicity (if available) will also be recorded in the study database. Your proposed treatment plan for NSCLC will be recorded too.

You will have a blood sample drawn. Less than 2 ounces of your blood will be taken.

If your study doctor does not yet know your EGFR gene status, additional blood will be drawn for EGFR gene testing, called GeneStrat testing, as part of your routine care and to assess whether or not you can participate in this study. If you have a certain EGFR gene mutation, you will not be able to participate in this study. You and your study doctor may also choose to order additionally available mutations as part of the GeneStrat test, including but not limited to EML4-ALK, BRAF, KRAS, ROS1, and RET. You and your study doctor will receive the results of the gene status test. The results will be placed in your medical record. (Genes are in your cells, and they are what make you different from everyone else.)

Assuming you are eligible to continue to participate, your blood sample will then be used to perform VeriStrat and the investigational research tests. You and your study doctor will be informed of VeriStrat results. However, you and your study doctor will not receive results from the research tests because they are still under development.

If you are a newly diagnosed patient with previous VeriStrat results at the time of consent, you will not have to have another VeriStrat test done in order to be enrolled in the study.

Later, at each change in your regular treatment for NSCLC, your study doctor will record details regarding your disease, your response to treatments, and your next proposed treatment plan into the study database. Less than two ounces of your blood will be drawn each time your treatment changes. Your study doctor may again choose to use GeneStrat and/or VeriStrat testing as part of your routine care. A small amount of this sample will also be used for research purposes. Your actual treatment plan will be documented once your test results are complete and reviewed by your study doctor.

You should talk to the study doctor about what the GeneStrat test results may mean to you. You should consider talking to a genetics counselor and your regular doctor about your DNA and how other factors affect your health as well.

You are not expected to need any time to recover from participating in this research.

4.0 Participant Responsibilities

There are no required visits or treatments for this study. At your regularly scheduled visits, your study doctor or study staff will enter relevant health and medical information into the study database. A blood sample will be taken if your treatment changes, and the sample may be used to perform VeriStrat, GeneStrat, and the research tests.

Your involvement in this study will last for 18 months. While you are in the study, you should tell the study doctor or study staff about any changes in your health or the way you feel.

Tell the study doctor or study staff if you want to stop being in the study at any time.

If the study doctor and study staff are unable to contact you after repeated attempts during the study, they may contact a person listed on the disclosure form on file at the study center for updated contact information or to learn about changes in your health.

5.0 Potential Benefits

You will not receive any direct benefits from your participation in this study.

Information from this study might help researchers compare outcomes in patients treated for NSCLC with various therapies and to understand whether the VeriStrat, immunotherapy, and/or GeneStrat tests help doctors determine how to treat NSCLC and/or determine the prognosis in patients with NSCLC.

6.0 Potential Risks

The physical risks and/or discomforts associated with this study are no more than your routine care for NSCLC that includes drawing blood from your vein. Some problems you might have from this are:

- pain
- bruising
- dizziness
- infection

There is a risk that someone could find your protected health information and identify you. We will do our best to keep this from happening by using a code of letters and numbers to protect your identity and the associated data and samples that are collected. The coded data may be saved for many years. You should ask the study doctor or study staff about how long your coded samples might be kept for the research.

It is possible that your insurance company, other doctors, and others may be able to see the genetic test results. A federal law called the Genetic Information Nondiscrimination Act (GINA) makes certain kinds of genetic discrimination illegal. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

7.0 Sponsor

Biodesix is paying for this research study, including payment to the investigator listed on page 1 of this form or the clinic (study center) for the time associated with their oversight and management of this study at the study center.

8.0 Expenses

You will not be financially responsible for any costs associated with VeriStrat, GeneStrat or the research tests. Your insurance company will be billed for GeneStrat or VeriStrat tests that your study doctor believes are medically necessary, but anything that is not reimbursed related to VeriStrat and GeneStrat will be covered by Biodesix. You and your insurance company will be responsible for the cost of any other medications or other tests not included in this study (as you would be normally).

9.0 Payments

<<Quorum will add site-specific compensation language to the form based on information the site reports to Quorum.>>

10.0 Alternatives to Being in this Study

This study does not provide treatment for your NSCLC. Your alternative is not to be in this study. Your decision to take part in this study will not change the care you receive from your regular doctor. Your decision to stop participation in this study will not affect the way your regular doctor will be treating you.

11.0 New Information

Your study doctor or study staff will let you know if new information becomes available that would affect your willingness to continue participating in this study.

12.0 Problems

If you become injured during this study, you will be treated according to your regular doctor's standard of care practices. If you suffer a study-related injury, the reasonable costs of necessary medical treatment of the injury will be reimbursed to the extent these costs are not covered by your private insurance or other third party coverage.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries.

You do not give up any of your legal rights by signing this form.

13.0 Contacts

You may ask questions about the study at any time. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions, concerns, or complaints about the study. If you get hurt or sick during the study and feel it is related to your participation in this study, you should call the study center at the phone number listed on page 1 of this form.

14.0 IRB

Quorum Review has reviewed and approved this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

15.0 Termination of Participation

Joining a study is voluntary. You can withdraw from the study at any time. Your decision will not affect your care in any way, either now or in the future, and there will be no penalty.

If you decide to withdraw from the study, please let your study doctor or the study staff know. The information collected up to the time that you withdraw from the study may still be used by the Biodesix to the extent permitted by applicable law, but no new information will be collected. If you stop being in the study early, the study doctor may ask you some questions about being in the study.

The study doctor or Biodesix can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You do not follow directions you have received about the study.
- Biodesix or a governmental entity with appropriate jurisdiction stops the study for any reason.

If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.

After you join the study, your study doctor might decide not to participate in the study any longer. Your study doctor will let you know if he/she decides not to participate in the study anymore. You will be informed of another study doctor you can contact with study-related questions for the rest of your participation if you choose to continue taking part in the study. If your study doctor changes, you will be notified and you may have to sign a new consent form.

16.0 Data Confidentiality

The United States government has issued a privacy rule to protect the privacy rights of patients and research participants. This rule was issued under a law called the Health Insurance Portability and Accountability Act

of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information. This section of the document, called an "Authorization," explains how your health information will be used and disclosed for the above study and describes your rights, including the right to see your health information.

During this study, the study center will need to use protected health information about you. Your protected health information is health information about you that could be used to identify you. This may include information in your medical records and information created or collected during the study. By signing this authorization, you allow the disclosure of your protected health information to carry out this study. If you do not sign this form, you cannot be in the study.

By signing this authorization, you also allow the release of your protected health information to the study investigators, and any representatives who work on behalf of them to conduct the study. Your information may also be given to Quorum Review, the U.S. Food and Drug Administration, and other government health agencies.

Your medical records and study records may be reviewed by the study sponsor, their representatives, regulatory authorities, and/or other oversight bodies such as Quorum Review and the FDA. The purpose of any review is to make sure the study is being conducted properly and that the data are collected correctly, or for other uses allowed by law.

After your information is shared with the people and companies listed above, the law may not require them to protect the privacy of your information.

The study sponsor may combine the study results with results of other studies to develop a better understanding of NSCLC and treatment for NSCLC. The information may be given to the FDA or other government health agencies as part of applications or to meet other reporting requirements. In no event will you be identified by name in any published reports about this study or any other scientific publications or presentations.

There is no way to ensure records are kept completely confidential, however steps will be taken to ensure it is as secure as possible.

To ensure the scientific integrity of the study, you agree that you may not be able to review some of your records related to the study until after the study has been completed. Once the study is completed, you will be able to review and obtain copies of your records related to the study.

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. The study doctor and study staff will still be able to use and share your information that they have already collected.

This authorization to use and share your information expires in 50 years.

You will receive a signed copy of this form for your records.

Signature of Participant

Date

17.0 Consent to Participate

I have read this form, and I have been able to ask questions about this study. My study doctor or the study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

I agree to the use and sharing of my records related to this study, as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I will receive a signed copy of this consent form for my records.

Printed Name of Participant

Signature of Participant

Date

I have fully explained this study to the participant. I have discussed its purpose, its procedures (if any), the possible risks and benefits, and the voluntary nature of participation. I have invited the participant to ask questions and have answered any questions the person has asked. I have given the participant a signed copy of this form.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date